FOOD AND DRUG ADMINISTRATION (FDA)

Pulmonary-Allergy Drugs Advisory Committee (PADAC)

Hilton Washington, DC/ Silver Spring
8727 Colesville Road Silver Spring, MD

November 18, 2009

DRAFT AGENDA

To discuss: BLA # 103976, Supplement # 5149 for Xolair (omalizumab), manufactured by Genentech/Novartis. The proposed indication for this product is to treat moderate to severe persistent asthma in patients between 6 and 11 years of age whose symptoms are inadequately controlled with inhaled steroid medications and have (a) a positive reaction to skin testing with common substances that can cause allergies and asthma, such as pollen, or (b) in vitro reactivity, which is measured with a blood test that confirms the presence of specific proteins consistent with allergies and asthma.

8:00 a.m.	Call to Order Introduction of Committee	Dennis Ownby, M.D. Acting Chair, PADAC
	Conflict of Interest Statement	Kristine Khuc, Pharm.D. Designated Federal Official, PADAC
8:15 a.m.	Opening Remarks	Badrul Chowdhury, M.D., Ph.D. Director, Division of Pulmonary and Allergy Products Center for Drug Evaluation and Research (CDER), FDA
8:30 a.m.	**Sponsor Presentation**	**Genentech/Novartis**
9:45 a.m.	Clarifying Questions for Sponsor	
10:00 a.m.	Break	
10:15 a.m.	**FDA Presentation**	
12:00 p.m.	Lunch	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Clarifying questions for FDA	
2:15 p.m.	Charge to Committee Discussion and Questions/Vote	
5:00 p.m.	Adjournment	

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